Remarks

Amendments to the Claims

Independent claims 1, 7, and 13 have been amended to recite "human" instead of "subject" and to recite "human PSD95." This amendment incorporates the subject matter recited in dependent claims 66-68, which have been canceled.

The amendments add no new matter, raise no new issues, and do not require a new search.

Rejection Under 35 U.S.C. § 112 ¶ 1 (written description)

The Final Office Action maintains the rejection of claims 1, 4-7, 10-13, 16-22, 24, 25, 34, 62, and 64 under 35 U.S.C. § 112 ¶ 1 as insufficiently described and extends the rejection to new claims 66-68. Claims 66-68 are canceled. Applicants respectfully traverse the rejection of the remaining claims.

The Final Office Action again contends that the specification's disclosure of an antisense oligonucleotide which is complementary to nucleotides 241-258 of the rat PSD95 nucleotide sequence (GenBank Accession No. M96853) does not sufficiently represent the recited genus of antisense oligonucleotides. To advance prosecution, claims 1, 7, and 13 have been amended to recite an antisense oligonucleotide which is complementary to mRNA encoding human PSD95. Human PSD95 mRNA was known in the art before the present application was filed. See the copy of Genbank Accession U83192 that accompanies this response.

The present specification, together with the knowledge in the relevant field, adequately describes the subject matter of claims 1, 4-7, 10-13, 16-22, 24, 25, 34, 62, and 64. Please withdraw the rejection.

Rejection Under 35 U.S.C. § 112 ¶ 1 (enablement)

The Final Office Action maintains the rejection of claims 1, 4-7, 10-13, 16-22, 24, 25, 34, 62, and 64 under 35 U.S.C. § 112 ¶ 1 as not enabled for their full scope and extends the rejection to new claims 66-68. Claims 66-68 are canceled. Applicants respectfully traverse the rejection of the remaining claims and address below the Examiner's response to their previous arguments.

First, the Final Office Action still contends the pending claims are too broad with respect to the recitations "subject," PSD95 mRNAs, and PSD95 PDZ domains. See page 16 ¶ 3 through page 17 ¶ 1. To advance prosecution, independent claims 1, 7, and 13 are now limited to humans and to antisense oligonucleotide which is complementary to mRNA encoding human PSD95.

Second, the Final Office Action contends that the art "recognizes significant obstacles and unpredictability, as discussed in the cited art" with respect to therapeutic use of antisense oligonucleotides. Page 17 ¶ 1. The cited art is Chirila,[1] Jen,[2] and Stein.[3] As Applicants pointed out in the previous response, all three references acknowledge that antisense therapy is not perfected in all aspects. Perfection, however, is not what is required for enablement. Applicants provided nine references that provided a sampling of the numerous clinical trials using a variety of antisense oligonucleotides that had been carried out and reported in the literature by the May 12, 2000 priority date of this application. The Final Office Action ignored those references, which weigh heavily in favor of enablement, because the references do not teach Applicants'

[1] Chirila *et al.*, "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides," *Biomaterials 23*, 321-42, 2002.

[2] Jen & Gewirtz, "Suppression of Gene Expression by Targeted Disruption of Messenger RNA: Available Options and Current Strategies," *Stem Cells 18*, 307-19, 2000.

[3] Stein, "Is irrelevant cleavage the price of antisense efficacy?" *Pharmacol. Therapeutics 85*, 231-36, 2000.

invention! See page 17 ¶ 2 ("the cited references do not teach the administration of the instant nucleic acid to treat the instantly claimed disease states, which is the substantive issue of the instant rejection."). By such logic, the Chirila, Jen, and Stein references are also not relevant.

The proper standard for determining whether the present specification meets the enablement requirement is whether any experimentation which may be needed to practice the methods of claims 1, 4-7, 10-13, 16-22, 24, 25, 34, 62, and 64 is undue or unreasonable. *In re Wands*, 858 F.2d 731, 736-37, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The Patent Office has not made a *prima facie* case that undue or unreasonable experimentation is needed to practice the claimed methods as amended.

Please withdraw the rejection.

Respectfully submitted,
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